



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

March 19, 2001

SUBJECT: 1,4-Bis(bromoacetoxy)-2-butene (BBAB): Risk Assessment and Science Support Branch's Response to Food and Drug Administration's Comments

FROM: Norm Cook, Chief
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TO: Connie Welch, Chief
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**Pesticide
Chemical**

No.: 035605

Chemical

Name: 1,4-Bis(bromoacetoxy)-2-butene (BBAB)

Case: 3030

Barcode: D271451

Introduction

On July 25, 2000, the Risk Assessment and Science Support Branch (RASSB) completed the Agency's Preliminary Risk Assessment (PRA), as well as all pertinent Science Chapters and Executive Summary, for 1,4-Bis(bromoacetoxy)-2-butene (BBAB) in support of the Agency's Reregistration Eligibility Decision

(RED). RASSB sent these documents to Regulatory Management Branch II (RMB-II), which then forwarded them to the Food and Drug Administration (FDA) for review and comment. On 12/19/00 FDA faxed the Agency their comments (12/14/00 memo) on the Agency's review of the BBAB label and the calculations used in the Agency's BBAB Dietary Exposure Chapter.¹ Specifically, FDA stated that:

1. Under Title 21 CFR 176.300 *Slimicides* FDA has cleared BBAB for use as a slimicide in process water used in the wet end of the paper making process, including finished paper intended to contact food;
2. FDA has not cleared BBAB for use in water-based, food-contact paper coating formulations;
3. FDA has no comments on the Agency's toxicology findings; and
4. FDA's dietary calculations are less conservative than USEPA's resulting in lower dietary residues and dietary exposure. These values are presented below.

Dietary Exposure Calculations

The dietary exposure calculations developed by FDA and USEPA are summarized as follows:

Dietary Exposure Calculations for 1,4-Bis(bromoacetox)-2-butene (BBAB)		
Agency	Dietary Concentration in Food	Estimated Daily Intake (EDI)
FDA	0.007 ppm or 7.000 ppb	2.100 ug BBAB/person/day
USEPA	0.600 ppm or 600.000 ppb	180.000 ug BBAB/person/day

As can be seen, USEPA dietary exposure calculations result in values eighty-six times (86x) higher than those of FDA. This is because FDA assumes that the majority, 98.8 %, of any slimicide (e.g., BBAB) applied during the wet end of the paper making process is removed in the water. However, in this situation USEPA assumes that none of the BBAB is removed in the water, all of the BBAB adheres to the paper, and all of the BBAB in the paper migrates into food.

RASSB Conclusions

¹ RASSB's Dietary Exposure Chapter for BBAB was originally submitted to RMB-II as Appendix 2: Dietary Exposure (barcode: D251933; electronic documents: D251933.mem; D251933.wpd).

RASSB has reviewed FDA's comments and dietary exposure calculations and has rereviewed the presently-registered BBAB label and RASSB's previous dietary exposure calculations. Based upon these efforts we offer the following:

1. RASSB concludes that FDA's comment concerning clarification of the coatings use on the BBAB label is appropriate.
2. RASSB has modified its Dietary Exposure Science Chapter to include a discussion of FDA's comments. However, RASSB has not modified its dietary exposure calculations because:
 - a. There is a lack of credible migration study data to utilize in the dietary exposure assessment. (NOTE: There is an existing migration study which provides contradictory results. One part of the study shows migration of BBAB residues into food-simulating solvents; the other part of the study shows no migration of BBAB residues.); and
 - b. BBAB has low water solubility, and based on this property RASSB concludes that BBAB may not be removed from the paper slurry into the water portion of the slurry during the paper-making process. Considering this, RASSB has not changed its original dietary exposure calculations for BBAB. These calculations result in maximum estimated residues of 0.600 ppm (600 ppb) BBAB in food and an Estimated Daily Intake (EDI) of 180 ug BBAB/person/day.

RASSB Recommendations

Considering the above conclusions, RASSB recommends the following to RMB-II:

1. The Agency should require the registrant to modify the BBAB label to prohibit BBAB's use in water-based, food-contact paper coating formulations;
2. The Agency should require the registrant to submit an acceptable food migration study using presently approved FDA migration study techniques. Submission of such data would provide data pertinent to an accurate determination of BBAB dietary exposure for food items. The registrant should utilize the latest FDA guidelines entitled, "RECOMMENDATIONS FOR CHEMISTRY DATA FOR INDIRECT FOOD ADDITIVE PETITIONS".

In closing, the above represents RASSB's response and reanalysis concerning FDA's comments. Attached is our revised Dietary Exposure Chapter for BBAB. If there are questions on the above, please feel free to contact me.

Attachments

cc: Jonathan Chen
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RASSB files